

Applicant: Van Tassel et al.
Serial No.: 09/382,275
Group Art Unit: 3738

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Docket No. 20220-311

CLAIM AMENDMENTS

Please cancel claims 74-75 without prejudice and disclaimer.

Please amend claims 1 and 58 as set forth below.

Please add new claims 82-87 as set forth below.

1. (Currently Amended) An implantable stent comprising a tubular stent body having a plurality of interconnected microholes distributed throughout said stent body substantially uniformly along the entire length of said stent body, said plurality of microholes being sufficiently small so as to promote an organized growth pattern of infiltrating cells throughout said stent body, and said stent body being otherwise substantially free of holes larger than said microholes.
2. (Original) The stent according to claim 1 wherein the organized growth pattern is angiogenesis.
3. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a plurality of depressions in the surface of at least a portion of the stent body.
4. (Withdrawn) The stent according to claim 3 wherein the depressions have an average volume per depression in the range from about 10 μm to about 100 μm .
5. (Withdrawn) The stent according to claim 3 wherein the depressions are in a regular pattern on at least the interior surface of the stent body.
6. (Withdrawn) The stent according to claim 5 wherein the pattern is a waffle weave.
7. (Withdrawn) The stent according to claim 5 wherein the pattern is selected to create turbulence in the flow of fluid through the stent body.
8. (Withdrawn) The stent according to claim 7 wherein the turbulence increases fluid shear stress upon the infiltrating cells.
9. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a plurality of longitudinal pleats, grooves or channels in the stent body.
10. (Withdrawn) The stent according to claim 9 wherein the pleats, grooves, or channels have an average height or depth in the range from about 10 μm to about

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100 μm and an average distance from center to center in the range from about 10 μm to about 100 μm .

11. (Withdrawn) The stent according to claim 9 wherein the pleats, grooves, or channels are spaced and sized to promote create fluid shear stress in flow of blood through the stent and/or to cause alignment of cells that infiltrate the pleats, grooves, or channels.

12. (Withdrawn) The stent according to claim 1 wherein the surface features comprise pores in the stent body having an average diameter in the range from about 30 microns to about 65 microns.

13. (Withdrawn) The stent according to claim 12 wherein the stent body is formed from a polymer or a non-woven matrix of metal fibers.

14. (Withdrawn) The stent according to claim 13 wherein the metal fibers are stainless steel, tantalum, elgiloy, nitinol, or a suitable combination thereof, and have a diameter in the range from about 1 micron to 25 microns.

15. (Withdrawn) The stent according to claim 13 wherein the non-woven matrix has a porosity of about 50% to about 85%.

16. (Withdrawn) The stent according to claim 15 wherein the porosity is at least about 70%.

17. (Withdrawn) The stent according to claim 1 wherein the surface features comprise an array of upstanding projections that promote shear turbulence in blood flow along at least a portion of the surface of the stent body.

18. (Withdrawn) The stent according to claim 17 wherein the projections have an average height of from about 10 μm to about 100 μm .

19. (Withdrawn) The stent according to claim 18 wherein the projections are an orderly array of hooks or stalks having a diameter to height ratio of from about 10:1 to about 100:1.

20. (Withdrawn) The stent according to claim 19 wherein the hooks or stalks have a uniform spacing of from about 10 μm to about 200 μm from center to center.

21. (Withdrawn) The stent according to claim 1 wherein the stent body is formed of a polymeric material having pores with an average pore diameter in the range from about 30 microns to about 65 microns.

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22. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a layer of a biocompatible substance that expands or thickens in an aqueous environment to assume a three-dimensional form, wherein the layer covers at least a portion of the surface of the stent body.

23. (Withdrawn) The stent according to claim 22 wherein the three dimensional form comprises an array of upstanding projections.

24. (Withdrawn) The stent according to claim 22 wherein the layer comprises a hydrogel.

25. (Withdrawn) The stent according to claim 22 wherein the three dimensional form is porous.

26. (Withdrawn) The stent according to claim 22 wherein the expandable substance is a hydrogel.

27. (Withdrawn) The stent according to claim 1 wherein the surface features comprise a pattern of hydrogel markings on at least a portion of the surface of the stent body.

28. (Withdrawn) The stent according to claim 27 wherein the pattern of markings comprises a plurality of dots, lines, curvilinear tracings, or a mixture thereof.

29. (Withdrawn) The stent according to claim 28 wherein the markings are distributed over the interior surface of the stent body.

30. (Original) The stent according to claim 1 wherein the stent is diametrically adjustable.

31. (Withdrawn) The stent according to claim 1 wherein the stent further comprises a transcutaneously energized heating mechanism attached to the stent body.

32. (Withdrawn) The stent according to claim 31 wherein the heating mechanism is adapted to controllably heat the stent to temperatures from about 38° C to about 49° C when the stent is implanted.

33. (Withdrawn) The stent according to claim 32 wherein the heating mechanism comprises a thermostat/heat regulator.

34. (Withdrawn) The stent according to claim 33 wherein the thermostat/heat regulator comprises one or more heat sensors and a telemetry device for conveying the temperature sensed by each sensor.

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35. (Withdrawn) The stent according to claim 34 wherein the telemetering device comprises an antenna coil wrapped about the surface of the stent and a hybrid integrated circuit chip in communication with the antenna coil, whereby energy picked up by the antenna coil powers the hybrid circuit.
36. (Withdrawn) The stent according to claim 34 wherein the thermostat/heat regulator comprises at least two heat sensors located at opposite ends of the stent body.
37. (Withdrawn) The stent according to claim 35 wherein the heat sensors have sufficient sensitivity to detect a temperature difference as small as 0.1° C from one end of the stent to the other end.
38. (Withdrawn) A stent system comprising a stent according to claim 1 in spaced juxtaposition to an energy source for transcutaneously applying energy to the stent, thereby causing the temperature of the stent to increase to a temperature above body temperature.
39. (Withdrawn) The stent system according to claim 37 wherein the energy source delivers electromagnetic energy to the stent in the form of radio frequency energy, microwave energy, or a magnetic field.
40. (Withdrawn) A stent system comprising a stent according to claim 37 in spaced juxtaposition to an energy source for transcutaneously applying energy to the stent, thereby causing the temperature of the stent to increase to the temperature from about 38° C to about 49° C.
41. (Withdrawn) The stent system according to claim 35 wherein each of the sensors produces a temperature output signal corresponding to the temperature sensed and wherein the stent system further comprises a monitor in spaced juxtaposition to the stent for transcutaneously receiving the output signal from each sensor.
42. (Withdrawn) The stent system according to claim 39 wherein the monitor is in communication with the energy source and signals from the monitor activate the energy source.
43. (Previously Presented) An active stent comprising a stent according to claim 1 and further comprising live cells growing in said interconnected microholes.

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44. (Previously Presented) The active stent according to claim 43 wherein the live cells are selected from the group consisting of endothelial cells, smooth muscle cells, leukocytes, monocytes, epithelial cells, polymorphonuclear leukocytes, lymphocytes, basophils, fibroblasts, stem cells, epithelial cells and eosinophils.

45. (Previously Presented) The active stent according to claim 44 wherein the live cells are smooth muscle cells, epithelial cells, or endothelial cells.

46. (Withdrawn) The active stent according to claim 43 wherein the stent further comprises a transcutaneously energized heating mechanism adapted to control the heating of the stent to a temperature sufficient to cause the live cells to increase production of one or more bioactive agents.

47. (Withdrawn) The active stent according to claim 46 wherein the bioactive agent stimulates angiogenesis and/or capillary formation.

48. (Withdrawn) The active stent according to claim 47 wherein the bioactive agent is vascular endothelial growth factor (VEGF), a fibroblast growth factor (FGF), angiopoietin 1, or thrombin.

49. (Withdrawn) The active stent according to claim 46 wherein the bioactive agent modifies vascular structure in the hematologic system.

50. (Withdrawn) The active stent according to claim 49 wherein the bioactive agent modifies platelet function.

51. (Withdrawn) The active stent according to claim 46 wherein the bioactive agent is an anti-proliferative, anti-restenotic, or apoptotic agent.

52. (Withdrawn) The active stent according to claim 51 wherein the bioactive agent is nitric oxide.

53. (Withdrawn) The active stent according to claim 46 wherein the agent increases production of nitric oxide in the cells in or around the stent.

54. (Withdrawn) The active stent according to claim 43 further comprising means carried by the stent body for telemetering stent temperature information to an external energy source.

55. (Withdrawn) An implantable stent comprising a tubular stent body and a heating mechanism attached to the stent body that includes one to about six temperature sensors attached at discrete spaced locations along the length thereof,

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each adapted for sensing the temperature of the stent at the discrete location, and a telemetering device for transcutaneously transmitting the output of the temperature sensors to an external monitor; wherein the stent body comprises metal or a dielectric substance.

56. (Withdrawn) The stent according to claim 55 wherein two of the temperature sensors are located at opposite ends of the tubular stent body.

57. (Withdrawn) The stent according to claim 55 wherein the temperature sensors are sensitive to temperature differences as small as 0.1° C.

58. (Currently Amended) A method for treating a tubular body organ in a subject in need thereof said method comprising:

promoting the ingrowth of living cells in a stent having a plurality of interconnected microholes distributed within said stent body substantially uniformly along the entire length of said stent body, said plurality of microholes being sufficiently small in size so as to promote ingrowth of the cells, and said stent body being otherwise substantially free of holes larger than said microholes. and,

implanting the stent into the tubular organ of the subject prior to or following the promoting of the ingrowth of the living cells so as to treat the tubular organ.

59. (Original) The method according to claim 58 wherein the living cells are donor or autologous cells.

60. (Original) The method according to claim 59 wherein the living cells are autologous.

61. (Original) The method according to claim 58 wherein the treatment further comprises promoting or inhibiting angiogenesis within the stent body.

62. (Original) The method according to claim 58 wherein the body organ is a blood vessel.

63. (Original) The method according to claim 58 wherein the treating comprises holding the cells in a specific pattern or stimulating the growth of the cells into an organized growth pattern.

64. (Original) The method according to claim 63 wherein the organized growth pattern develops into an organized cellular structure within the stent body.

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65. (Withdrawn) The method according to claim 58 wherein the stent can be heated by transcutaneously applied energy and the method further comprises transcutaneously energizing the heating of the stent to a temperature above normal body temperature sufficient to cause the living cells to express one or more bioactive agents.

66. (Withdrawn) The method according to claim 65 wherein the one or more bioactive agents promotes or inhibits angiogenesis within the living cells growing in the stent.

67. (Withdrawn) The method according to claim 65 wherein at least some of the living cells contain a DNA construct encoding and expressing a bioactive agent under the control of an operatively associated exogenous heat shock promoter.

68. (Withdrawn) The method according to claim 67 further comprising turning the promoter on or off by controlling the heating of the stent.

69. (Withdrawn) The method according to claim 65 wherein the temperature to which the stent body is heated remains below a value lethal to the living cells.

70. (Withdrawn) The method according to claim 69 wherein the temperature to which the stent body is heated is in a range from about 38° C to about 49° C.

71. (Withdrawn) The method according to claim 67 wherein the heat shock promoter is derived from *E. Coli* or *Drosophila*.

72. (Withdrawn) The method according to claim 67 wherein the treating further comprises chronically releasing the bioactive agent on demand by transcutaneously energizing the stent.

73. (Original) The method according to claim 58 wherein the living cells are endothelial cells, smooth muscle cells, leukocytes, monocytes, polymorphonuclear leukocytes, lymphocytes, basophils, fibroblasts, stem cells, epithelial cells or eosinophils.

74. (Cancelled) A therapeutic device adapted for implantation within a body lumen of a mammal in need thereof comprising:

a lumen wall-contacting member comprising a tubular structure expandable to a predetermined diameter following implant thereof in a body lumen to support said body lumen, the tubular structure having surface features sized and/or

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patterned to promote and organized growth pattern of infiltrating cells therein following implant into the body lumen; and

means for administering a stimulus to the cells growing in the surface features of the tubular structure from a source external to the mammal, thereby stimulating release of bioactive agents by the cells to the lumen wall.

75. (Cancelled) The therapeutic device according to claim 74 wherein the wall-contacting member is a vascular stent.

76. (Withdrawn) A method for measuring flow of a fluid through a body lumen, said method comprising:

implanting a stent according to claim 34 into a body lumen having a flow of fluid therethrough,

energizing the implanted stent transcutaneously to raise the temperature thereof above body temperature,

monitoring transcutaneously the output from one or more of the temperature sensors upon cessation of the energizing to determining the cooling rate at each of the one or more sensors, and

obtaining the flow rate of the fluid through the stent from the cooling rate at the one or more sensors.

77. (Withdrawn) The method according to claim 76 wherein the temperature of the stent is raised from 0.1° C about 12° C above body temperature.

78. (Withdrawn) The method according to claim 76 wherein the fluid is blood and the stent is implanted in a blood vessel.

79. (Withdrawn) The method according to claim 76 wherein the cooling rate is determined at least two of the sensors and the flow rate is obtained as a function of the distance between the two sensors.

80. (Withdrawn) The method according to claim 76 wherein the cooling rate is determined using the temperature difference between at least two of the temperature sensors.

81. (Withdrawn) The method according to claim 76 wherein the method is repeated periodically to monitor occlusion of the lumen.

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82. (Newly Added) The stent according to claim 1, wherein said stent body is penetrated with said microholes.

83. (Newly Added) The stent according to claim 1, wherein said stent body is formed from a three dimensional non-woven matrix.

84. (Newly Added) The stent according to claim 1, wherein said microholes extend throughout said stent body so as to promote cell growth outward into said stent tube and into attachment with cells at either end of said stent.

85. (Newly Added) The method according to claim 58, wherein said stent body is penetrated with said microholes.

86. (Newly Added) The method according to claim 58, wherein said stent body is formed from a three dimensional non-woven matrix.

87. (Newly Added) The method according to claim 58, wherein after the implanting of said stent, said ingrowth of living cells is promoted such that said cells grow outward into said stent tube and into attachment with cells at either end of said stent.